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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,840	01/05/2006	Yoshinobu Morimoto	Q88695	2260

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/540,840	MORIMOTO ET AL.	
	Examiner	Art Unit	
	Melissa S. Mercier	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 6-27-05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending in this application. Claims 1-15 are rejected.

Priority

Applicants claim of priority to PCT/JP03/17050 is acknowledged.

Information Disclosure Statement

Receipt of the Information Disclosure Statement received on June 27, 2005 is acknowledged.

Specification

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Claim Objections

Claims 3-4 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1-2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 12 is objected to under 37 CFR 1.75 as being a substantial duplicate of claims 13.

Claim 14 is objected to under 37 CFR 1.75 as being a substantial duplicate of claims 15.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 15 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pigmentations caused by a drug, does not reasonably provide enablement for any pigmentation present on the skin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-10, 12, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-10 provides for the use of a composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Regarding Claims 12 and 14, it is unclear to the Examiner what applicant is intending to whiten. Clarification is requested. The examiner is interpreting these claims to be a method of whitening the skin.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

(The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10 and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bissett (US PGPub 2001/0012853).

Bissett discloses, "a composition for topical application and for regulating skin condition, including regulating non-melanin discoloration of skin" (paragraph 0031).

According to Bissett, the composition can comprise "N-acetyl-L-cysteine and derivatives thereof, L-ascorbic acid and derivatives, and tranexamic acid" (paragraphs 0018-0049).

With regard to Claims 2, 4, 6, and 8, according to MPEP 2144.05 II A Optimization within Prior Art Conditions or Through Routine Experimentation, differences in concentration will not support the patentability of subject matter encompasses by the prior art unless there is evidence indicating such concentrations are critical. Where the general conditions of a claim are disclosed in the prior art, it is

not inventive to discover the optimum or workable ranges by routine experimentation. "The normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where the disclosed set of percentage ranges is the optimum combination of percentages." (Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382)

Claims 1-10 and 12-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Ancira et al. (US PGPub 2004/0137077).

Ancira discloses, a composition for the treatment of seborrheic keratosis comprising at least one melanin inhibitor. Examples of such melanin inhibitors include gamma-L-Cysteine and tranexamic acid" (paragraph 0034).

With regard to Claims 5 and 7 Ancira teaches, "to aid in moisturizing or conditioning the skin, as will be known to those of skill in the art in view of the instant disclosure. For example, other ingredients may be added to improve the skin condition or the effectiveness of the compositions. Vitamins may added to the compositions to aid in improving the skin condition thereby inhibiting the production of subsequent cutaneous anomalies after treatment of the original condition" (Ancira, paragraph 0063). Ancira further discloses the vitamin may be L-ascorbic acid (0032).

With regard to claims 12-15, Ancira discloses methods of seborrheic keratosis removal, the compositions are also effective in removing other skin conditions such as

hyper pigmentation" (paragraph 0062). It is the examiners position that the removal of hyper pigmentation is the same as whitening the skin and treating pigmentations.

With regard to Claims 2, 4, 6, and 8, according to MPEP 2144.05 II A Optimization within Prior Art Conditions or Through Routine Experimentation, differences in concentration will not support the patentability of subject matter encompasses by the prior art unless there is evidence indicating such concentrations are critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. "The normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where the disclosed set of percentage ranges is the optimum combination of percentages." (Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382)

Claims 1-4 and 11 rejected under 35 U.S.C. 102(e) as being anticipated by Rath (US Patent 6,974,833).

Rath discloses, "compositions and methods for the treatment of diseases or pathological states related to the degradation of the extra cellular matrix" (abstract).

Rath's Table 1 discloses dosages of Components in the Compositions for Oral Administration. The components comprise: tranexamic acid (1-1500 mg/kg BW/d) and cysteine (0.1-5,000 mg/kg BW/d) (column 6, lines 40-50).

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MSMercier

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